Attachment D

Consultations Summary for the Renewal ICR, entitled "Labeling Requirements for Certain Minimum Risk Pesticides under FIFRA Section 25(b) Information Collection Request"

OMB No. 2070-0187; EPA No. 2475.03; Docket No. EPA-HQ-OPP-2018-0139

Representatives contacted from the following companies:

- Bonide Products, Inc.
- W. Neudorff GmbH KG
- Spectrum Brands

EPA received feedback from one company (Bonide Products) during the consultation request period. The questions asked, and the comments received, are provided below.

Questionnaire and Responses:

(1) Frequency of Collection

Products entering the market that are fully compliant with the minimum risk exemption at 40 CFR 152.25(f), including the labeling requirements, are exempt from federal registration requirements. The Agency does not collect information on products that meet all of the minimum risk exemption requirements. However, this collection contains third-party disclosures in the form of product labeling, which is mandated under regulation. Therefore, the frequency of the collection (i.e., labeling requirements) cannot be reduced while maintaining an exemption status.

- EPA assumes this is a one-time burden for labeling new products entering the minimum risk pesticide market. Do you believe that EPA's assumption is correct? If not, please provide an explanation. Agree
- (2) Clarity of Instructions

This ICR is intended to account specifically for the labeling burdens associated with complying with the minimum risk exemption requirements. In particular, the exemption requires respondents to provide certain information on the label so that the Agency, other regulatory agencies (i.e., the States), and consumers can utilize them.

• Based on the instructions (regulations, PR Notices, guidances, websites, etc.), is it clear what you are required to do and how to label products in order to comply with the federal exemption requirements? If not, what suggestions do you have to clarify the instructions to help reduce labeling burdens associated with minimum risk exemption compliance? It is difficult to decipher what qualifies as a commonly consumed food commodity as an inert ingredient. It would be nice to have some further clarification.

- Considering that there is no required labeling format, is it difficult to label products in ways that are clear, logical, and easy to complete? We did not have any troubles with this.
- Would examples of labels or labeling formats be useful in helping you comply with the labeling requirements of the exemption? An image of exactly how the ingredient statement should be formatted would be helpful.
- (3) Burden and Costs

Since EPA does not register minimum risk products, the Agency has assumed that the paperwork burdens for labeling new products in this renewal ICR will be similar to those approved in the currently approved ICR.

- Are there other labeling paperwork activities that the Agency has not taken into account for new minimum risk products? If so, what other activities should EPA consider in renewing this ICR? The company that produces the labels imposes a charge for changes that are made. For example, if the ingredient statement is changed, there will be a charge of up to \$5,000 dollar in plate changes if the product is packaged in a Polyethylene Bag. These figures can vary depending on the type of label and the label changes but most times these change charges cost significantly more than the labor hours.
- Are the labor wage rates accurate? If you disagree, please provide information to support an alternative estimate.
- The Agency assumes there is no capital cost associated with this activity. Is that correct? If not, please provide an explanation of the capital costs the Agency has missed in this ICR.
- Bearing in mind that the burden and cost estimates include only burden hours and costs associated with the labeling activities described in this ICR (e.g., the ICR does not include estimated burden hours and costs for conducting studies since this information is not required to be submitted to EPA), are the estimated burden hours and costs per response accurate? If you provide burden and cost estimates that are substantially different from EPA's estimates, please provide an explanation of how you arrived at your estimates.
- Are there other costs that should be accounted for that may have been missed?